

 a shaft having a proximal end, a distal end, a guidewire lumen extending between the proximal and distal ends, and a stent bed proximate the distal end upon which a self-expanding stent is mounted; and

a sheath defining an interior volume, the sheath having a proximal end, a distal end, and an enlarged section proximate the distal end, the sheath being coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed, the sheath being formed from an inner polymeric layer, a lubricious coating on the inner polymeric layer, an outer polymeric layer, and a flat wire reinforcement layer.

IN THE DRAWINGS

The Examiner is requested to approve the changes to the drawings as shown in red on the copy of Figures 11 and 12 attached to the accompanying Request For Approval of Drawing Amendment.

REMARKS

In response to the Office Action mailed September 17, 2002, Applicants amend their application and request reconsideration in view of the amendment and the following remarks in this Reply. Claims 1 and 8 were amended, no claims have been added or cancelled so that claims 1-15 remain pending. No new matter has been introduced.

The Examiner objected to the drawings for failing to comply with 37 CFR 1.84(p)(5). Accordingly, a drawing amendment correcting the deficiencies noted is proposed. Specifically, reference numeral 70 has been changed to 60, which is referenced in the specification. Corrected Formal Drawings will be submitted upon approval of the corrections.

The Examiner objected to the drawings for failing to comply with 37 CFR 1.84(p)(4) because reference characters "18" and "26" have both been used to designate the distal end of the shaft. Applicants respectfully draw the Examiner's attention to page 10, line 10, wherein it is stated that the distal portion of the shaft is designated by reference character "26". The distal end is designated by reference character "18."

Claims 1-15 were rejected under 35 U.S.C. § 112, second paragraph. Applicants have amended claims 1 and 8 in accordance with the Examiner's instructions. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-2 and 6-7 were rejected as anticipated by U.S. Patent Number 6,425,898 to Wilson et al. (hereafter Wilson). This rejection is respectfully traversed.

Wilson discloses a delivery apparatus for a self-expanding stent. The delivery apparatus comprises a sheath, a shaft located coaxially within the sheath, a radiopaque fluid injection annular gap and a self-expanding stent. The sheath includes a tubular member formed from an outer polymeric layer, an inner polymeric layer and a wire reinforcing layer.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in independent claim 1, is directed to a delivery apparatus for a self-expanding stent. The apparatus comprises a substantially tubular shaft and a substantially tubular sheath. The substantially tubular sheath having a proximal end, a distal end, and an enlarged section proximate the distal end. The sheath is coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed of the shaft. The sheath is formed from an inner polymeric layer, an outer polymeric layer, and a flat wire reinforcement layer.

Wilson fails to disclose or suggest "a flat wire reinforcement layer" as is claimed in independent claim 1. The flat wire of the present invention reduces the profile of the sheath without sacrificing strength or flexibility. Since Wilson fails to disclose or suggest a "flat" wire reinforcement layer, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 3-5 were rejected as being unpatentable over Wilson in view of U.S. Patent Number 5,176,660 to Truckai (hereinafter Truckai). This rejection is respectfully traversed.

Truckai discloses a catheter having reinforcing strands. The flexible catheter comprises at least one resilient, tubular layer in telescoping relation with a tubular sheath made of helically disposed crossing strands. The tubular sheath of helical strands is sealed between inner and outer resilient, tubular layers.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or

suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Applicants respectfully submit that the cited prior art references, whether taken alone or in combination fail to disclose or suggest all of the claim limitations. Wilson fails to disclose or suggest a flat wire reinforcement layer. Truckai discloses a tubular sheath made of helically disposed crossing strands. Truckai fails to disclose a sheath having embedded therein a flat wire reinforcing layer. The flat strands of Truckai cross and overlap to form the sheath. Applicants also respectfully submit that there is simply no motivation or suggestion to modify the apparatus of Wilson based on the teachings of Truckai. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 8-15 were rejected as being unpatentable over Wilson in view of U.S. Patent Number 4,705,511 to Kocak (hereinafter Kocak). This rejection is respectfully traversed.

The present invention, as claimed in independent claim 8 is directed to a delivery apparatus for a self-expanding stent. The apparatus comprises a shaft having a proximal end, a distal end, a guidewire lumen extending between the proximal and distal ends, and a stent bed proximate the distal end upon which the self-expanding stent is mounted, and a sheath defining an interior volume, the sheath having a proximal end, a distal end, and an enlarged section proximate the distal end, the sheath being coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed, the sheath being formed from an inner polymeric layer, a lubricious coating on the inner polymeric layer, an outer polymeric layer, and a flat wire reinforcement layer.

Kocak discloses a flexible tube for the introduction of catheters and like devices into a vascular system. The system essentially comprises a connector body having an inlet and an outlet, a flexible tube for intravenous use at the outlet and a thin cylindrical wall prepared from a protective coating.

Applicants respectfully submit that the cited prior art references, whether taken alone or in combination, fail to disclose or suggest all of the claim limitations. Neither reference discloses a flat wire reinforcing layer and neither reference discloses a lubricious coating on the inner polymeric layer of a sheath of a delivery apparatus for a self-expanding stent. Applicants also respectfully submit that there is simply no motivation or suggestion to modify the apparatus of Wilson based on the teachings of Kocak. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants would be willing to interview the present case if the Examiner so desires. Accordingly, the Examiner is invited to call the undersigned at (732) 524-2518 if such a call would facilitate the prosecution of this application.

A favorable action on the merits is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,



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Version With Markings To Show Changes Made

IN THE CLAIMS

Please amend the claims as follows:

1. (Amended) A delivery apparatus for a self-expanding stent comprising:

a substantially tubular shaft having a proximal end, a distal end, a guidewire lumen extending between the proximal and distal ends, and a stent bed proximate the distal end upon which [the] a self-expanding stent is positioned; and

a substantially tubular sheath defining an interior volume, the sheath having a proximal end, a distal end, and an enlarged section proximate the distal end, the sheath being coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed, the sheath being formed from an inner polymeric layer, an outer polymeric layer, and a flat wire reinforcement layer.

8. (Amended) A delivery apparatus for a self-expanding stent comprising:

a shaft having a proximal end, a distal end, a guidewire lumen extending between the proximal and distal ends, and a stent bed proximate the distal end upon which [the]a self-expanding stent is mounted; and

a sheath defining an interior volume, the sheath having a proximal end, a distal end, and an enlarged section proximate the distal end, the sheath being coaxially positioned over the shaft such that the enlarged section is aligned with the stent bed, the sheath being formed from an inner polymeric layer, a lubricious coating on the inner polymeric layer, an outer polymeric layer, and a flat wire reinforcement layer.